DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

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NOV - 5 2001

WARNING LETTER

VIA FACSIMILE
VIA FEDERAL EXPRESS

Peter Klein
Chief Executive Officer
Diomed Incorporated
1 Dundee Park
Andover, Massachusetts 01810

Re: Diomed Lasers

Dear Mr. Klein:

The Food and Drug Administration (FDA) has reviewed promotional material for the Diomed Diode and Photodynamic Therapy Lasers at the website http://www.diomed-lasers.com. These products are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). For the reasons discussed below, the claims that Diomed, Inc. (Diomed) has made on its website has resulted in the misbranding and adulteration of both of these devices.

The Diomed laser has been cleared for marketing under various premarket notifications, including:

- Diomed 15/30/60W Surgical Diode Laser (K962354), intended for use in ablation, incision, excision, coagulation, and vaporization of soft tissue in open and endoscopic surgical procedures, including contact and non-contact use for additional soft tissue applications of general surgery, ophthamology/oculoplastic surgery, urology, gastroenterology, gynecology, otorhinolaryngology, pulmonary/thoracic surgery, dermatology/plastic surgery, neurosurgery (coagulation only), and orthopedic surgery;
- LaserLite Diode Surgical Laser (K980142), intended for incision, excision, vaporization, ablation, cutting, hemostasis and coagulation of soft tissue in dermatology and plastic surgery, including aesthetic surgery; uses expanded to include treatment of pigmented and vascular lesions including leg veins (K981090);
- DioScan (LiteScan) Scanning Handpiece Accessory (K990014), indicated for incision, excision, vaporization, ablation, cutting, hemostasis, and coagulation of soft tissue in dermatology and plastic surgery, including aesthetic surgery, and
- A100 Aesthetic Diode Laser (K000982), indicated for incision, excision, vaporization, ablation, cutting, hemostasis, and coagulation of soft tissue in dermatology and plastic surgery, including aesthetic surgery, and treatment of pigmented and vascular lesions including leg veins.

The Center for Devices and Radiological Health (CDRH) has granted premarket approval for the Diomed 630 PDT laser, model T2USA. That device was approved under PMA P990021 for use in Photodynamic Therapy with PHOTOFRIN® as a source of activation of PHOTOFRIN® for: a) palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with ND: YAG laser therapy b) reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial nonsmall cell lung cancer (NSCLC), and treatment of microinvasive endobronchial NSCLC in patients for whom surgery and radiotherapy are not indicated. Diomed has also submitted to CDRH a premarket application approval (PMA) for its Diomed 652 PDT Laser although that device has not received approval at this time.

As described below, the Diomed website is essentially unchanged from the website we initially reviewed this past June. Our June 4, 2001 letter to Diomed advised you of the objectionable claims on the website at that time. We sent a follow-up response to Richard Walker, Quality & Regulatory Director, dated July 9, 2001, in which we noted that we found the majority of his responses to our June letter and Diomed's corrective measures unacceptable. We indicated that your firm's proposed remedies did not bring your website into compliance. Most of the corrective actions consisted of merely adding "disclaimer" statements in an attempt to continue to promote the devices and/or uses absent the required premarket regulatory review.

Subsequent to your receipt of our letters, Diomed submitted to the Office of Device Evaluation (ODE) a 510(k), K012398, on July 27, 2001, for varicose vein treatment. The 510(k) is a modification of your previously cleared Diomed Diode laser. The 510(k) is required under the Center's regulations at 21 CFR 807.81(a)(3)(ii) because the varicose vein claim represents a significant modification in the intended use of the product. Although this intended use has not received clearance, there are numerous claims throughout your web site for this indication. Diomed's US website homepage states, "Major U.S. Media Outlets Feature Diomed's New EVLT Treatment for Varicose Veins." In addition to this violative heading, the site still contains the *Aesthetic Buyers Guide* article entitled "Diomed Pioneers EndoVenous Varicose Vein Treatment" and the Good Morning America (GMA) article which also discusses EVLT for varicose veins. (Although Diomed did not make the claims in this article, you are responsible for the statements in that you have chosen to provide the article to your readers). There are two other press releases which discuss the EVLT for varicose veins, an April 14, 2001, news release entitled "Diomed's EVLT Treatment Called 'innovative Therapy' by leading trade publications" and a May 18, 2001, news release, entitled "Diomed Launches International Website." The May 18, article includes the following statement, "Diomed's new EndoVenous Laser Treatment, (EVLT) for the treatment of varicose veins with the Diomed 810nm laser...*." The text is asterisked to indicate that the "EVLT is currently proceeding through the approval process and is not yet available."

Your website also contains a link to a *New York Times* article entitled, "Now, Easier Ways to Eliminate Varicose Veins." A portion of the text of this article states, "The laser has not yet been cleared by the Food and Drug Administration to treat varicose veins, although it has been approved for other purposes." The "About Diomed" and "Product Catalog" links also include a similar impermissible claim, "Applications such as a new minimally invasive treatment of varicose veins that is less painful and has a faster recovery time."

FDA's regulations at 21 CFR 801.4 provide that the intended use of a device refers to the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by such persons' expressions or may be shown by circumstances surrounding the distribution of the article. This objective intent may be shown by, for example, labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. As noted above, the promotion of your lasers for the treatment of endovenous varicose veins constitutes a major change or modification of its intended use. As noted above, a major change or modification in the intended use requires the submission of premarket notification, as provided in the agency's regulations at 21 CFR 807.81(a)(3)(ii).

The failure of Diomed to submit that required premarket notification has resulted in the misbranding and adulteration of the Diomed Diode Lasers. The Diomed Diode Lasers are misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by section 510(k) of the Act and the device was not found to be substantially equivalent to a predicate device.

The Diomed Diode lasers are also adulterated within the meaning of section 501(f)(1)(B) because they are class III devices, as defined by section 513(f) of the Act, for which there are in effect neither approved premarket approval applications under section 515(a) of the Act nor approved investigational device exemptions under section 520(g) of the act.

Your website at http://www.diomed-lasers.com is directed (through a US link) to your domestic audience for domestic sales. Although the need for delineation between information directed towards domestic and international audiences was discussed in our prior correspondence, inappropriate content on the US portion of your site remains. In your "Product Catalog" brochure there is a discussion of "Interventional Radiology." The asterisked material in this brochure refers the reader to the following disclaimer, "Not approved for this indication in the US." As we indicated previously, the use of disclaimers does not change the character of the material as being a claim for an uncleared or unapproved use.

In a prior correspondence, it was indicated that some of the discussions regarding the off-label use of Diomed 's laser were presented in abstracts or peer-reviewed journal articles. Sections 551-557 of the Act establish the legal framework for the distribution of certain types of information beyond the scope of the intended use of the legally marketed device. In certain circumstances, companies may distribute, in response to an unsolicited request, information concerning off-label uses of legally marketed devices. We refer you to sections 551-557 of the Act and to Part 99 of FDA's regulations, as well as to the Agency's March 16, 2000 Federal Register notice, which describes FDA's interpretation of the role of those sections of the Act and regulations. We consider the presentation on your website of the off-label information to be a change in the intended use of the cleared Diode laser.

This letter is not intended to be an all-inclusive list of deficiencies associated with your device. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may also be reflected in other promotional materials used by your firm. You are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to correct promptly these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil money penalties.

Please notify this office in writing, within 15 working days of your receipt of this letter, of the specific steps you have taken to correct the noted violations. Your response should include steps taken to address any misleading information currently in the marketplace and to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Ms. Patricia L. Jahnes, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-300), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's New England District Office. Please send a copy of your response to the District Director, Food and Drug Administration, New England District Office, One Montvale Avenue, 4th Floor, Stoneham, Massachusetts 02180.

Finally, the Photodynamic Therapy lasers' section still contains content that promotes devices that have not received clearance or approval. In a previous response, you indicated that you continue to maintain such content on your website, in an attempt to solicit partners for "appropriate trials/IDE programs" which would use your laser products. You include the following "disclaimers" in an attempt to mitigate the promotional nature of their representations.

"For research use only"
"No FDA approvals for investigational use on human subjects"
"This product is currently used in clinical trials in conjunction with ANTRIN (motexafin lutetium) Injection for Photoangioplasty for treatment of atherosclerosis, and with LUTRIN for treatment of a variety of cancers. It is the light source for activating the drug. Caution: Investigational device – Limited by Federal Law to investigational use"

[redacted]

As indicated previously, we find your use of such disclaimers ineffective and again we suggest that you contact our Division of Bioresearch Monitoring at 301-594-4718 to discuss the appropriate scope and format for any discussion of clinical trails and investigational devices.

Sincerely yours,

Larry Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health